

PACKAGE LEAFLET: INFORMATION FOR THE USER

## Quinine Sulfate 200 mg Tablets

Quinine Sulfate

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet:

1. What Quinine Sulfate Tablets are and what they are used for
2. What you need to know before you take Quinine Sulfate Tablets
3. How to take Quinine Sulfate Tablets
4. Possible side effects
5. How to store Quinine Sulfate Tablets
6. Contents of the pack and other information

### 1. What Quinine Sulfate Tablets are and what they are used for

Quinine Sulfate is one of a group of medicines called antiprotozoal agents.

Quinine Sulfate Tablets are used to:

- Treat malaria
- Treat and prevent nocturnal (night-time) leg cramps in adults and the elderly when sleep is regularly disturbed.

### 2. What you need to know before you take Quinine Sulfate Tablets

#### Do not take Quinine Sulfate Tablets if you:

- Are allergic to quinine or any of the other ingredients of this medicine (listed in section 6)
- Suffer from tinnitus (ringing or buzzing in the ears)
- Have problems with your eyes or difficulty seeing
- Suffer from inflammation of the optic nerve causing problems with your eye sight
- Have blood in the urine (haemoglobinuria)
- Suffer from a particular type of muscle weakness (myasthenia gravis).

#### Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Quinine Sulfate Tablets if you:

- Are sensitive to Quinine. See section 4 for possible symptoms
- Have had malaria for a long time
- Have irregular heartbeats or other heart disease
- Have conduction defects of the heart (this is where the heart cannot conduct electrical signals properly)
- Suffer from severe glucose-6-phosphate dehydrogenase deficiency (G6PD), this can cause episodes of anaemia after eating certain foods such as fava beans or certain drugs to prevent malaria or dapsone
- Intend on using the medicine for nocturnal leg cramps
- Have previously experienced any adverse reaction to quinine, including that in tonic water or other beverages. Quinine may cause thrombocytopenia (reduction in blood platelet counts)
- Suffer from kidney or liver problems.

You should not take more than the prescribed dose as a condition called 'cinchonism' may occur even with a normal dose. Please see section 4 'Possible side effects' for symptoms of cinchonism and tell your doctor if you experience any of them.

Tell your doctor if you were born with or have any condition that causes an abnormal heart rhythm.

### Children and adolescents

Quinine Sulfate Tablets are not suitable for children weighing less than 20kg or less than 5 years old.

### Other medicines and Quinine Sulfate Tablets:

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, especially:

- Anticoagulants such as warfarin (to stop your blood clotting)
- Cardiac glycosides (medicines for your heart such as digoxin)
- Chloroquine, artemether with lumefantrine or mefloquine, halofantrine or primaquine (also to treat malaria)
- Cimetidine (to treat stomach ulcers or acid reflux and indigestion)
- Flecainide, quinidine or amiodarone (to treat irregular heart rhythms)
- Pimozide or thioridazine (to treat some mental disorders)
- Rifampicin or moxifloxacin (antibiotics)
- Barbiturates (e.g. phenobarbital), carbamazepine or phenytoin (medicines to treat epilepsy)
- Oral hypoglycaemics (to treat diabetes)
- Ciclosporin (used following transplant surgery and to treat various inflammatory diseases)
- HIV protease inhibitors (drugs to treat HIV infections such as ritonavir)
- Amantadine (an antiviral to treat influenza and Parkinson's disease)
- Suxamethonium (a muscle relaxant used in surgery, tell the anaesthetist you are taking Quinine Sulfate Tablets)
- Medicines to treat fungal infections (fluconazole, itraconazole, ketoconazole).
- Medicines which are known to cause disturbances in heart rhythm
- Terfenadine (used in the treatment of allergies).

If you see another doctor or go into hospital, let them know what medicines you are taking.

### Pregnancy and breast-feeding

Do not take the tablets if you are pregnant, trying to become pregnant or breast-feeding unless advised to by your doctor. Quinine Sulfate Tablets should not be used for night cramps during pregnancy. Consult your doctor or pharmacist if in doubt.

### Driving and using machines

Quinine may affect your vision or cause vertigo (a feeling of dizziness or 'spinning').

If you are affected, DO NOT drive or operate machinery.

### Quinine Sulfate Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, i.e. is essentially 'sodium-free'

### 3. How to take Quinine Sulfate Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. These tablets should be swallowed with some water.

#### Malaria

#### Adults (including the elderly) and adolescents over 12 years:

600mg at 8 hour intervals for 7 days.

#### Children under 12 years:

10mg/kg at 8 hour intervals for 7 days.

Quinine Sulfate Tablets are not suitable for children weighing less than 20kg or less than 5 years old.

#### Nocturnal leg cramps

#### Adults (including elderly people):

200mg at bedtime. The maximum dose is 300mg.

Do not take more than the prescribed dose.

It may take up to 4 weeks before you notice any reduction in the frequency of leg cramps.

Dimension: 180 x 270 mm

Front Side

### ARTWORK DETAIL LABEL

|                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                             |               |             |                 |      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|---------------|-------------|-----------------|------|
| <b>Product</b>                                                                                                                                                                                                                                                                                                                                                     | <b>QUININE SULPHATE TABLETS BP 200 mg</b>                                                                   |               |             |                 |      |
| Buyer/Country                                                                                                                                                                                                                                                                                                                                                      | Strides Pharma UK Ltd.                                                                                      | Component     | Pack Insert |                 |      |
| Dimension                                                                                                                                                                                                                                                                                                                                                          | 180 x 270 mm - Same Size                                                                                    |               |             | Pack            | ---- |
| New Item Code                                                                                                                                                                                                                                                                                                                                                      | 1043444                                                                                                     | Old Item Code | 1036421     |                 |      |
| Colour Shades                                                                                                                                                                                                                                                                                                                                                      | ■ BLACK                                                                                                     |               |             | No. of Colours  | 1    |
| Change Control No.                                                                                                                                                                                                                                                                                                                                                 | PC-TSG/2022/050 - Record No.: 333166                                                                        |               |             | Artwork Version | 4.0  |
| Design/Style                                                                                                                                                                                                                                                                                                                                                       | Front & Back Printing. To be supplied unfold.                                                               |               |             |                 |      |
| Substrate                                                                                                                                                                                                                                                                                                                                                          | 60 GSM Paper.                                                                                               |               |             |                 |      |
| Special Instructions                                                                                                                                                                                                                                                                                                                                               | PRINTING CLARITY TO BE CLEAR AND SHARP.                                                                     |               |             |                 |      |
| Autocartonator Requirements                                                                                                                                                                                                                                                                                                                                        | <b>Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.</b> |               |             |                 |      |
| <b>Caution to the printer:</b> Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. <b>DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.</b> |                                                                                                             |               |             |                 |      |

During this time your doctor should monitor you to make sure that the medicine is suitable for you. He/she should monitor you at three monthly intervals thereafter. From time to time, your doctor may stop treatment with quinine sulfate to see if the condition returns or worsens.

**Patients with kidney or liver problems**

A lower dose than the recommended adult dose or increased time between doses should be used if you have kidney or liver problems.

**If you take more Quinine Sulfate Tablets than you should**

If you accidentally take more than your prescribed dose, contact your nearest hospital casualty department, or tell your doctor, immediately. Take any remaining tablets and the container with you.

An overdose of quinine may cause 'cinchonism'.

Early symptoms are:

- Tinnitus (ringing in the ears), impaired hearing and vision, headache, feeling sick, being sick, fits
- Rashes, confusion, hot and flushed skin.

More severe symptoms include:

- Nervous system disorders, stomach problems, shallow breathing, loss of consciousness
- Severe eyesight problems including blindness
- Effects on the heart, kidney and brain
- Shock, low blood sugar.

Large doses can cause abortion.

**If you forget to take Quinine Sulfate Tablets**

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time. If you are elderly, it is particularly important to take this medicine exactly as directed by the doctor.

**If you stop taking Quinine Sulfate Tablets**

Continue to take the tablets for as long as your doctor tells you to. If you are taking them for malaria you must take the full course. If you stop too soon the infection may recur.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible Side Effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reaction - itchy skin rash, swelling of the lips, face, throat or tongue, flushing, fever, asthma or sensitivity to light
- Unexplained bruising or bleeding or frequent nose bleeds
- A serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson Syndrome).

Contact your doctor at once if the following effects occur:

- Cinchonism - abdominal pain, diarrhoea, disturbed vision (blurred vision, changes in colour perception or field of vision or total blindness), headache, feeling or being sick, ringing in the ears or impaired hearing, rashes, loss of consciousness, fits, shock due to heart problems, irregular heartbeats, death. If these occur while taking Quinine Sulfate Tablets for leg cramps, treatment should be stopped and a doctor contacted straightaway
- Changes to blood cells, if you notice that you have more sore throats and infections than usual tell your doctor who may want to give you a blood test.

If you feel unwell whilst taking Quinine Sulfate for night cramps, stop taking the tablets and talk to your doctor immediately.

The following side effects have also been reported:

- Diarrhoea, feeling or being sick, abdominal pain, low blood sugar
- Muscle weakness, excitement, agitation, 'spinning' sensation, confusion, loss of consciousness, coma, death

- Headache, change in vision, 'ringing' in the ears, loss of hearing
- Swollen, itchy, flaky, red or raised patches of skin, rashes, sensitivity to light
- Kidney damage, water retention, slowed heart rate, changes in heart rhythm and the way the heart beats, eczema, miscarriages (at very high concentrations), difficulty breathing
- Aggravation of myasthenia gravis
- Excretion of protein in your urine which may cause a colour change
- Fall in blood pressure coupled with a weak pulse.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Quinine Sulfate Tablets**

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date stated on the label. The expiry refers to the last day of that month. Remember, this medicine is for you only. Never give it to anyone else. It may harm them, even if their symptoms are the same as yours.

Do not use this medicine if you notice visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the Pack and Other Information**

**What Quinine Sulfate Tablets contain**

The active substance(s) is Quinine Sulfate.

The other ingredients are:

- Lactose
- Microcrystalline cellulose
- Maize starch
- Colloidal anhydrous silica
- Purified talc
- Magnesium stearate
- Sodium starch glycollate
- Ingredients for coating: Hypromellose, Opadry white Y-1-7000 (containing methylhydroxy-propylcellulose, titanium dioxide, polyethylene glycol 400) Carnauba Wax

**What Quinine Sulfate Tablets look like and contents of the pack**

Description:

White colored circular biconvex film-coated tablet, plain on both sides.

The tablets are supplied in PVC/aluminium foil blister packs containing either 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 56, 60, 84, 90, 100, 112, 120, 168, 180, 250 or 500 tablets. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer Strides Pharma UK Ltd.**

Unit 4, Metro Centre, Tolpits Lane, Watford, Herts, WD18 9SS, UK

**This leaflet was last revised in 05/2022.**



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Dimension: 180 x 270 mm

Back Side

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